

Appl. No. 09/940,471
Am dt. dated November 17, 2005
Reply to Office Action of September 1, 2005

REMARKS

Applicants have received and carefully reviewed the Office Action mailed September 1, 2005.

In paragraphs 3-4 of the Office Action, claim 195 was rejected under 35 U.S.C. §112, second paragraph, for lacking antecedent basis for the "step of sensing an abnormality". Claim 195 has been amended to simply recite an additional step of determining whether the patient has an abnormally slow heart rate. It is believed that this amendment overcomes the §112, second paragraph rejection.

In paragraph 6 of the Office Action, claims 205, 206, and 209 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,825,871 to Cansell. After careful review, Applicants respectfully disagree.

The Examiner specifically states that contact with the heart is avoided in the reference by its inclusion of one or more of items 8, 8', or 100. Elements 8 and 8' are "petals", and Cansell explains, the petals, after insertion, "elastically unfold to return to their natural orientation which ensures that the electrode 5 is separated from the wall of the heart." (Column 6, lines 48-50.) It appears to Applicants that the petals perform their function by contacting the heart walls to keep the electrode away from the heart walls. The alternative, item 100, is a rolled up elastic insulating element, which also contacts the wall of the heart in order to keep the electrode away from the wall of the heart.

Applicants note that claim 205 particularly recites providing a lead system having one or more electrodes for the device, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart. The claim does not merely state that the electrode does not contact the patient's heart, but instead, recites that the lead system, which includes more than merely the electrode, does not contact the patient's heart. A lead system includes a lead, with a conductor passing therein, an electrode coupled to the conductor, and anything coupled to the lead, for example, anchoring devices used to hold it in a desired location. The petals 8, 8', or the rolled up spacer element 100 shown by Cansell are part of the lead system, as they are coupled to the lead and hold it in a desired juxtaposition with respect to the heart. Therefore, the examples disclosed by Cansell include lead systems that contact the patient's heart, since the elements 8, 8' or 100 each contact the heart.

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Claim 206 also recites providing a lead system provided such that it is disposed internally to a patient without contacting the patient's heart, and like analysis applies with respect to this portion of the claim. Applicants have amended claim 206 to clarify that it is intended that a means for dispensing current is disposed on the device. The language merely recites where the means is located, but does not provide a specific structure to such means, and thereby does invoke §112, paragraph 6.

Claim 209 also recites providing a lead assembly such that it does not contact the patient's heart. Again, Cansell does not disclose a lead assembly that does not contact the patient's heart, as each lead assembly does include a spacing element that contacts the patient's heart.

In light of the above, it is believed that each of claims 205, 206 and 209 are patentable over Cansell.

In paragraph 8 of the Office Action, claim 195 was rejected under 35 U.S.C. §103(a) as being unpatentable over Cansell in view of U.S. Patent No. 4,940,054 to Grevis et al. As discussed above, claim 206, from which claim 195 depends, is believed to be patentable over Cansell at least because the lead assembly of Cansell includes spacers that do in fact contact the patient's heart. The Grevis et al. reference is merely cited as discussing detection of an abnormally slow heartbeat. However, the rejection does not further address the disposition of a lead assembly such that it does not contact the heart, and it is believed that a *prima facie* case of unpatentability has not been presented. Therefore, Applicants request withdrawal of the rejection.

In paragraphs 10-12, double patenting rejections were stated with respect to claims 201-202, 204 and 205, each citing commonly assigned U.S. Patent No. 6,856,835. Attached hereto is a terminal disclaimer that overcomes the double patenting rejections.

Applicants note that the Examiner states, on page 6, "internally to a patient and not contacting the patient's heart" is broader than "exclusive of the patient's heart." Without acquiescing to a particular interpretation, Applicants feel it is incorrect to state than one term or the other is broader/narrower. The terms are distinct, as indicated by differing positions taken by the Examiner in the present application and copending and commonly assigned U.S. Patent Application No. 09/940,378.

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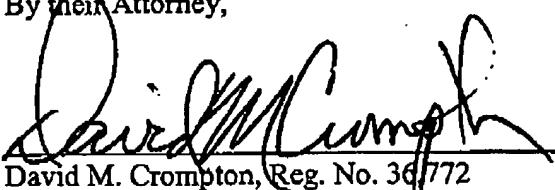
Applicants thank the Examiner for indicating the allowability of claims 203, 210-211, and 213-217.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
William J. Rissmann et al.

By their Attorney,

Date: 11/17/05


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